



A REVOLUTION IN GLOVE TECHNOLOGY

ORANGE

BIOLOGICAL  
RISK

TECHNICAL  
INFORMATION

SHIELDskin™  
ORANGE NITRILE™ 300 Sterile



★★★★★  
GENERAL  
RISK

★★★★★  
BIOLOGICAL  
RISK

★★★★☆  
CHEMICAL  
RISK

- ⇒ Powder-free ambidextrous extra length (300 mm / 11.8") sterile nitrile/neoprene protective gloves.
- ⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.
- ⇒ Fully compliant to the latest EU PPE norms relating to protective gloves against chemicals, micro-organisms and viruses.

#### DESCRIPTION

FORMULATION	Nitrile and neoprene synthetic rubber (acrylonitrile butadiene and polychloroprene).
DESIGN	Orange (Outer)/ White (Inner), ambidextrous, beaded cuff, textured fingertips.
PACKAGING	1 pair per PE peel pouch - 20 pouches per sealed poly bag - 8 poly bags per PE bag per carton.

#### SIZES

SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
CODES	67 6351	67 6352	67 6353	67 6354	67 6355	67 6356

#### STANDARDS


CE REGISTRATION	PPE Category III (Complex Design) - Regulation (EU) 2016/425.
EU PPE NORMS	EN 420:2003+A1:2009, EN 421:2010, ISO 374-1:2016+A1:2018, EN 374-2:2014, ISO 374-4:2013, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDD NORMS <sup>1</sup>	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.
USA STANDARDS	ASTM D3767-03 (2014), ASTM D573-04 (2015), ASTM D412-16, ASTM D6978-05 (2019) and IEST-RP-CC005.4 (2013).
OTHER STANDARDS	EN1149-1/2/3 & 5, ISO 21171:2006, ISO 11137-2:2015, ISO 10993-10:2010.

<sup>1</sup> With reference to Council Directive 93/42/EEC for Medical Devices

#### QUALITY

QUALITY ASSURANCE	Production management in accordance with ISO 9001:2015 and ISO 13485:2016.
TECHNOLOGY	twinSHIELD™ double-walled protection to offer a stronger glove and to reduce risk of pinholes. Two colours: orange to make it easier to select according to the risk, combined with a soft and comfortable white interior.

#### DOCUMENTATION

DECLARATION OF CONFORMITY	These documents can be freely downloaded from the product page on our website: <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> .	
EU TYPE EXAMINATION CERTIFICATE		
PRODUCT INSERT		
CERTIFICATE OF CONFORMANCE	To access CoC and Col, you need to be registered. Please contact us at <a href="mailto:info@shieldscientific.com">info@shieldscientific.com</a> or call your SHIELD Scientific representative.	
CERTIFICATE OF IRRADIATION		

# PHYSICAL PROPERTIES



NOMINAL THICKNESS		mm <sup>2</sup>	mil	Norm
⇒	Finger	0.17	6.7	ASTM D3767-03 (2014)
⇒	Palm	0.14	5.5	
⇒	Cuff	0.10	3.9	

<sup>2</sup> Thickness (+/- 0.03 mm)

LENGTH		Minimum	Typical	Norm
⇒	From middle finger tip to edge of cuff	≥ 290 mm / 11.4"	300 mm / 11.8"	EN 420:2003+A1:2009

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
	⇒	Before aging	≥ 6.0N    14 Mpa	≥ 500%	
⇒	After aging	≥ 6.0N    14 Mpa	≥ 400%	8.0N	

FREEDOM FROM HOLES		Performance	Norm
⇒	Acceptable Quality Level (AQL)	< 0.25 <sup>3</sup> - Level 3	EN 374-2:2014

<sup>3</sup> AQL as defined per ISO 2859-1:1999 for sampling by attributes.

# PROTECTION PROPERTIES

RISKS	Description	Norm
MICRO-ORGANISMS	1000 ml water test. Performance level 3, AQL < 0.25 (inspection level G1).	EN 374-2:2014
VIRUSES	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
CHEMICALS	<u>Performance</u> : Type B (JKPT). <u>Permeation</u> : Extensively tested. Online chemical resistance guide on <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> . <u>Degradation</u> : Tested for determination of resistance to degradation by chemicals.	ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018  EN 374-4:2013
RADIOACTIVITY	Protection from radioactive contamination.	EN 421:2010
ESD	Tested for electrostatic properties.	EN 1149-1/2/3 & 5
CLEANLINESS	Compatible with sterile processing. Typical value: < 3.000 particles per cm <sup>2</sup> and at 0.5 µm.	IEST-RP-CC005.4 (2013)
DNase and RNase CONTAMINATION	DNase and RNase free.	MO BIO Certification
STERILITY	Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10 <sup>-6</sup> .	ISO 11137-2:2015
ENDOTOXINS	Low endotoxin content at < 20 EU/pair - Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.	EN 455-3:2015
CYTOTOXIC	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)

ALLERGIES	
BIO-COMPATIBILITY	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010.
ACCELERATORS	Accelerator-free to minimize the risk of allergic contact dermatitis (also known as Type IV, delayed hypersensitivity or chemical allergy).
CHEMICAL ALLERGENS	Non-detectable levels using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
RESIDUAL POWDER	Powder-free to minimize the potential consequences of powder-borne dermatitis. Residual powder content is 1.0 mg/glove (typical) with a limit of 2.0 mg/glove (ISO 21171:2006).
LATEX PROTEIN	Latex-free.



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